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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,454	01/05/2004	Jean-Paul Renard	045636-5058	9282

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EXAMINER	
WOITACH, JOSEPH T	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,454	RENARD ET AL	
	Examiner	Art Unit	
	Joseph T. Woitach	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application filed January 5, 2004, is a 371 national stage filing of PCT/FR00/02698, filed September 29, 20000, which claims benefit to foreign application 99/12287 filed October 1, 1999 in France.

Applicants' preliminary amendment filed April 1, 2002 has been received and entered. Claims 1-12 have been canceled. Claims 13-24 have been added. Claims 13-24 are currently under examination.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on September 29, 2000. It is noted, however, that applicant has not filed a certified copy of the French application as required by 35 U.S.C. 119(b).

It is further noted that review of the preliminary examination report (IPER) of 01.10.1999 indicated that the priority document was not filed with the PCT. See feuille 1 PCT/IPEA/409 or page 12 of the document that includes the translation.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on January 5, 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." More specifically, it is noted that there are multiple citations throughout the specification. While it appears that many have been provided in the filed IDS, some have not for example Thompson et al 1998 (specification page 4). It is noted that a complete one to one comparison has not been made. Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

Claim 24 is objected to because of the following informalities:

The limitations of claim 24 are understood, however generally are not terms of art used to define such limitations. For example, ovine race or goat family are not commonly used, and a bit unclear to what is encompassed by a race or family in conjunction sheep and goats. It is also noted that claim 24 recites "Bovini" which is a recognized tribe of the family of Bovidae, however Bovidae is usually the term and breadth such embodiments are directed.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claim 13 is vague and unclear to what is "reconstituted", and incomplete because while the preamble indicates a method for the reconstitution of an embryo the method steps only involve steps of treating a donor cell. The preamble implies that the donor is transferred to recipient cytoplasm, and dependent claims set forth potential specific methodology (claims 19-22) however an embryo can not be formed by placing a donor nuclei into a cytoplasmic fraction. Further, the claim is unclear in the recitation of "controlled proteolysis" because what and how proteolysis is performed is not clearly set forth in the claim, nor in the present specification. Even in light of dependent claims that set forth specific enzymes to be used (claims 14 and 15), it is unclear what is being affected or to what extent, except the exclusion that histone proteins are not affected.

Claim 16 is vague and unclear in the recitation of "with the molecular weight greater than 20 000" because no units of weight are provided with the number. Additionally, it is unclear to what embodiment this applies, any polyanion in general or just polyaspartic acids listed last.

Claim 22 is unclear and confusing in the recitation of "cytoplasm in the interphase state" because cytoplasm do not have or represent such a state. The metes and bounds of the claim are indefinite because what is materially encompassed by this limitation is not clearly set forth in the claim nor the specification.

It is noted that dependent claims are included in the rejection because they fail to further clarify the specific basis of the rejections set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 13-17 are rejected under 35 U.S.C. 102(b) as being anticipate by Kraemer *et al.* (IDS reference).

Claim 13 encompasses method steps wherein any form of proteolysis and swelling of the nucleus are accomplished, where the dependent claims set forth that they enzymes are the serine proteases typsin or chymostrypsin. Kraemer *et al.* teach the isolation of nuclei and the analysis of various factors on nuclear swelling. In the specific teaching of isolation, the nuclei are isolated from liver tissue extracts by homogenization which would release the proteases into the composition. Since there is no specific limitation in the claim to what is controlled or what the end point of step (a) is, this general release anticipates this step. Kraemer *et al.* teach the use of polyanion induced swelling and more specifically a form of heparin which was purchased from Sigma that was 16,2000 (page 570). Without any specific limitation to size recited in the claim the broadest reasonable interpretation must be given to include essentially any molecular weight compound. With respect to premeabilization required of claim 17, this was affected during the process as evidenced by the fact that nuclei were isolated free of the cytoplasmic fraction (page 569).

Claims 13-15, 17 are rejected under 35 U.S.C. 102(b) as being anticipate by Aaronson *et al.* (JCB 62:746-754, 1974).

The breadth of the claims are summarized above. Aaronson *et al.* teach the isolation of nuclei and the affects of the detergent triton X-100 on isolated nuclei. The specific teaching of isolation describes that the nuclei are isolated from liver tissue extracts by homogenization which would release the proteases into the composition. Since there is no specific limitation in the claim to what is controlled or what the end point of step (a) is, this general release anticipates this step. Aaronson *et al.* teach the use of Triton X-100 which would result in the swelling of the nuclei. With respect to premeabilization required of claim 17, this was affected during the process as evidenced by the fact that nuclei were isolated free of the cytoplasmic fraction (page 569).

Claims 13-15, 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Wangh *et al.* (US Patent 6,753,457 B2).

Wangh *et al.* teach methods of reprogramming nuclei for a variety of applications including for use in generating nuclear transfer units to clone whole animals form somatic cell nuclei (see section IX, column 31 for example). More specifically, as directed to the instantly claimed methods, Wangh *et al.* teach optimization steps where donor cell nuclei were isolated and treated with trypsin (claim 15) and lysolecithin (claim 18). With respect to the step (b) for swelling, this was effectively accomplished during the isolation of the nuclei and the presence of

detergents in the isolation buffers. Finally, among the various methods known and used to introduce an isolated nuclei, Wangh *et al.* teach the use of microinjection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 13-15, 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wangh *et al.* (US Patent 6,753,457 B2).

The anticipation of claims13-15, 17-19 over Wangh *et al.* are discussed above. Briefly, Wangh *et al.* teach optimization steps where donor cell nuclei were isolated and treated with trypsin (claim 15) and lysolecithin (claim 18), and methods of using the isolated nuclei as a donor in nuclear transfer methodology. Wangh *et al.* teach that any animal, in particular mammals, can be generated using the method of nuclear transfer and specifically reduce to practice the use of microinjection. However, Wangh *et al.* fails to teach other methods of cell fusion or specific species of mammals such as cows, pigs and sheep. At the time of filing methods of practicing insertion of the donor cell into the recipient oocyte were performed by various methods and devices conventional to a particular laboratory. Similarly, at the time of filing the specific mammals that were the subject of research and being generated by nuclear transfer were sheep, cows and pigs. The present disclosure indicates that any method for nuclear transfer known in the art can be used and would adapted to the methods of treating the nuclear

donor cell as instantly claimed, therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the methods of Wangh *et al.* generally disclosed for generating ungulates such as cows, pigs and sheep, as well as use the methods established to most effectively generate the NT unit for each of these mammals. One having ordinary skill in the art would have been motivated to substitute for microinjection other methods such as electrofusion because of the success in a particular species of animal, ease over microinjection or availability of equipment in a given laboratory. Similarly, the generation of a particular mammal would be obvious and dependent on an individuals research model. The instant disclosure relies of the methods of nuclear transfer known in the art at the time of filing, so there would have been a reasonable expectation of success given the results of Wangh *et al.* and those generally known in the art for the use of other NT transfer methods and for the production of other mammals.

Thus, the claimed invention as a whole was clearly *prima facie* obvious.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

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